IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL a corporation of Barbados, Plaintiff, v. ANDRX PHARMACEUTICALS, LLC and ANDRX CORPORATION, Defendants.	C.A. Nos. 05-586 (GMS) 05-730 (GMS) 06-620 (GMS) (CONSOLIDATED) **REDACTED PUBLIC VERSION**

FINAL PRETRIAL ORDER

VOLUME 1

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BIOVAIL LABORATORIES INTERNATIONAL SRL a corporation of Barbados, Plaintiff, v. ANDRX PHARMACEUTICALS, LLC and ANDRX CORPORATION, Defendants.	)	C.A. Nos. 05-586 (GMS) 05-730 (GMS) 06-620 (GMS) (CONSOLIDATED) **CONFIDENTIAL** **FILED UNDER SEAL**

FINAL PRETRIAL ORDER

This matter having come before the Court at a pretrial conference held pursuant to Fed. R. Civ. P. 16, and Morris, Nichols, Arsht & Tunnell LLP, 1201 North Market Street, Wilmington, Delaware 19899, (302) 658-9200, and Paul, Hastings, Janofsky & Walker LLP, 75 East 55th Street, New York, New York 10022, (212) 318-6000, having appeared as counsel for Plaintiff Biovail Laboratories International SRL ("Biovail") and Potter Anderson & Corroon LLP, 1313 N. Market Street, Wilmington, Delaware 19899, (302) 984-6000, and Foley & Lardner LLP, 3000 K Street, N.W. Suite 500, Washington, D.C. 20007-5143, (202) 672-5300, having appeared as counsel for Defendants Andrx Pharmaceuticals, LLC and Andrx Corporation (collectively "Andrx") the following actions were taken:

I. JURISDICTION

This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.* This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a). Subject matter jurisdiction is not disputed.

II. STIPULATION AND STATEMENTS

The following stipulations and statements were submitted and are attached to and made a part of this Order:

A. Statement of Uncontested Facts

1. The parties stipulate to the facts listed in the attached Exhibit 1.

2. These proposed stipulated facts require no proof at trial and will become part of the evidentiary record in the case.

B. Statements of Contested Issues of Fact and Law

1. Biovail's statement of contested issues of fact and law is attached as Exhibit 2.

2. Andrx's statement of contested issues of fact and law is attached as Exhibit 3.

C. Exhibit Lists

1. Biovail's list of exhibits and Andrx's objections to Biovail's list of exhibits are attached as Exhibit 4.

2. Andrx's list of exhibits and Biovail's objections to Andrx's list of exhibits are attached as Exhibit 5.

3. Subject to the remaining provisions of this Order, no party may use an exhibit not present on its exhibit list absent good cause shown.

4. Each party reserves the right to use exhibits from the other party's trial exhibit list, even if not separately listed on its own exhibit list. However, recognizing that a party has a right to object to use of its own listed exhibits by the other side, the parties have agreed that all such objections are preserved and need not be disclosed in advance of trial.

5. Each party reserves the right to offer exhibits not set forth in its exhibit list for purposes of impeachment. In addition, each party reserves the right to offer exhibits that are not set forth on its exhibit list for use during the rebuttal case of the other party. Each party also reserves the right to add, for good cause shown, additional exhibits to its exhibit list.

6. Notwithstanding any contrary provisions in this Order, the parties will disclose and exchange copies of demonstrative and summary exhibits in accordance with the following procedure. The parties shall exchange complete color representations of all demonstrative exhibits no later than 6:00 pm the day before they are used in Court. This paragraph shall not apply to demonstratives created during testimony or argument at trial or to the ballooning, highlighting or excerpting of documents marked as exhibits.

7. Any exhibit identified on a party's exhibit list and not objected to is deemed to be admissible and may be entered into evidence by that party, except that

nothing herein shall be construed as a stipulation or admission that the document is entitled to any weight in deciding the merits of this case.

8. The parties stipulate to the authenticity of all exhibits, except where specifically indicated with the specific reasons for the objection noted. Any objection to a document's authenticity must be made in this Pretrial Order.

9. Legible copies of United States patents and the contents of United States and foreign patents and translations thereof (if in English or translated into English) may be offered and received in evidence in lieu of certified copies thereof, subject to all other objections which might be made to the admissibility of certified copies.

D. Witness Lists

1. Biovail's list of the names and addresses of the fact and expert witnesses that it intends to call at trial is attached as Exhibit 6.

2. Andrx's list of the names and addresses of the fact and expert witnesses that it intends to call at trial is attached as Exhibit 7.

3. Any witness not listed in the exhibits referenced above will be precluded from testifying absent good cause shown, except that each party reserves the right to call such rebuttal witnesses (who are not presently identifiable) as may be necessary, on reasonable notice to the opposing party.

4. For those depositions that have been videotaped, a party may introduce the deposition excerpt by videotape instead of or in addition to by transcript. If a party opts to introduce deposition testimony by videotape, any counter-designations of that same witness's deposition testimony must also be submitted by videotape. When

deposition designation excerpts are introduced, all admissible deposition counter-designation excerpts, whether offered by video-tape or by transcript, will be introduced simultaneously in the sequence in which the testimony was originally given. To the extent such designations are read or played in open court, each party will be charged for the time taken to read or play its designations, as measured by the proportion of lines of testimony for its designations to the total number of lines of testimony read or played.

5. Each party will provide to the other party the name and order of any witness that it intends to call to testify, whether live or by deposition testimony, no later than 6:00 p.m. two days prior to the day the witness is expected to testify. Objections to any such witness shall be provided by 6:00 p.m. the following evening.

E. Expert Witnesses

1. Biovail's statement setting forth the qualifications of each of its expert witnesses, any objections by Andrx thereto, and the subject matter of each expert witness's testimony are attached as Exhibit 8.

2. Andrx's statement setting forth the qualifications of each of its expert witnesses, any objections by Biovail thereto, and the subject matter of each expert witness's testimony are attached as Exhibit 9.

F. Deposition Designations, Objections and Counter-designations

1. Biovail's list of deposition designations, Andrx's objections to Biovail's designations, Andrx's counter-designations, and Biovail's objections to such counter-designations are attached as Exhibit 10.

2. Andrx's list of deposition designations, Biovail's objections to Andrx's designations, Biovail's counter-designations, and Andrx's objections to such counter-designations are attached as Exhibit 11.

G. Special Damages

This case does not involve any claims for damages.

H. Waivers of Claims and Defenses

1. Andrx will not present any evidence of invalidity with respect to the '866 patent.

I. Jury Trial Matters

This case will not be tried to a jury.

J. Proposed Findings of Fact and Conclusions of Law

1. Biovail's Proposed Findings of Fact and Conclusions of Law are attached in duplicate as Exhibit 12.

2. Andrx's Proposed Findings of Fact and Conclusions of Law are attached in duplicate as Exhibit 13.

K. Settlement Negotiations

There have been discussions between the parties concerning settlement, but the parties have not reached an agreement to date. It is unknown whether future discussions are likely to be productive.

L. Discovery

Discovery in this action is complete.

M. Motions *In Limine*

The Court's May 31, 2007 Scheduling Order (D.I. 187) provides that no motions *in limine* will be filed.

III. TRIAL SCHEDULE

This case is currently scheduled for a five-day trial, beginning at 9:00 a.m. on November 13, 2007. Biovail requests that the Court set aside at least an additional three days for trial.

IV. TYPE OF TRIAL

This is a non-jury trial.

V. NUMBER OF JURORS

This is a non-jury trial.

VI. ORDER CONTROLS THE COURSE OF TRIAL

This Order will control the course of the trial and may not be amended except by consent of the parties and the Court, or by order of the Court to prevent manifest injustice.

VII. POSSIBILITY OF SETTLEMENT

Possibility of settlement of this case was considered by the parties.

SO ORDERED this _____ day of November, 2007.

_____
United States District Judge

Jointly submitted by,

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs Louden

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EXHIBIT 1

EXHIBIT 1 TO PRETRIAL ORDER

THE PARTIES' STIPULATION OF UNCONTESTED FACTS

1. Plaintiff Biovail Laboratories International SRL ("Biovail") is a corporation organized and existing under the laws of Barbados, and has a place of business in Carolina, Puerto Rico.

2. Defendant Andrx Pharmaceuticals, LLC ("Andrx LLC") is a limited liability company organized under the laws of Delaware, and maintains a principal place of business at 4955 Orange Drive, Davie, Florida 33314.

3. Defendant Andrx LLC is a wholly-owned subsidiary of defendant Andrx Corporation ("Andrx Corp."), which is a corporation organized under the laws of Delaware that maintains a principal place of business at 4955 Orange Drive, Davie, Florida 33314.

4. United States Patent No. 5,529,791 (the "'791 patent"), entitled "Extended Release Form of Diltiazem," issued on June 25, 1996 to Galephar P.R., Inc., Ltd., the assignee of named inventors Arthur M. Deboeck and Philippe R. Baudier.

5. Biovail is the exclusive licensee of the '791 patent under a September 1995 Agreement, which remains in full force and effect, and Biovail has the exclusive right to sublicense others and to sue for past and present infringement.

6. United States Patent No. 7,108,866 (the "'866 patent"), entitled "Chronotherapeutic Diltiazem Formulations and the Administration Thereof," issued on September 19, 2006 to Biovail, the assignee of the named inventors Kenneth Stephen Albert and Paul José Maes.

7. Biovail owns all right, title and interest in the '866 patent, including the right to sue for past and present infringement.

8. Biovail is the holder of New Drug Application ("NDA") No. 21-392, by which the United States Food & Drug Administration ("FDA") first granted approval for 120 mg, 180 mg, 240 mg, 300 mg, 360 mg, and 420 mg extended release tablets including the active ingredient diltiazem hydrochloride (the "Cardizem® LA products"). These tablets are marketed in the United States under the tradename Cardizem® LA, and are indicated for the treatment of hypertension, and the management of chronic stable angina.

9. The '791 and '866 patents are listed in the FDA's Orange Book for Biovail's Cardizem® LA products.

10. On April 22, 2005, Andrx filed with the FDA Abbreviated New Drug Application ("ANDA") 77-686, including a certification with respect to the '791 patent under § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to market and sell a generic version of Cardizem® LA 420 mg tablets prior to the expiration of the '791 patent.

11. On or about June 22, 2005, Andrx sent a notice letter to Biovail, among others, in which Andrx represented that it had filed an ANDA for a generic version of Cardizem® LA 420 mg tablets, and that it sought approval of its ANDA prior to the expiration of the '791 patent. Biovail received a copy of Andrx's notice letter on or about June 27, 2005.

12. On August 10, 2005, within 45 days of receipt of Andrx's June 22, 2005 notice letter, Biovail filed suit against Andrx in this Court, C.A. No. 05-586, alleging that Andrx's filing of ANDA No. 77-686 constituted an act of patent infringement pursuant to 35 U.S.C. § 271(e)(2) and that the commercial manufacture, use, sale, offer for sale

and/or importation of Andrx's proposed ANDA products would infringe one or more claims of the '791 patent.

13. On August 30, 2005, Andrx filed with the FDA an amendment to ANDA No. 77-686 ("Amended ANDA"), including a certification with respect to the '791 patent under § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to market and sell generic versions of Cardizem® LA 120 mg, 180 mg, 240 mg, 300 mg, and 360 mg tablets prior to the expiration of the '791 patent.

14. On or about August 30, 2005, Andrx sent a notice letter to Biovail, among others, in which Andrx represented that it had filed the Amended ANDA No. 77-686 for generic versions of Cardizem® LA 120 mg, 180 mg, 240 mg, 300 mg, and 360 mg tablets ("Amended ANDA"), and that it sought approval of its Amended ANDA prior to the expiration of the '791 patent. Biovail received a copy of Andrx's notice letter on or about September 2, 2005.

15. On October 14, 2005, within 45 days of receipt of Andrx's August 30, 2005 notice letter, Biovail filed suit against Andrx in this Court, C.A. No. 05-730, alleging that Andrx's filing of the Amended ANDA No. 77-686 constituted an act of patent infringement pursuant to 35 U.S.C. § 271(e)(2) and that the commercial manufacture, use, sale, offer for sale and/or importation of Andrx's proposed Amended ANDA products would infringe one or more claims of the '791 patent.

16. On or about September 19, 2006, Andrx filed with the FDA a second amendment to ANDA No. 77-686 (the "Second Amended ANDA"), including a certification with respect to the '866 patent under § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to market and sell generic versions

of Cardizem® LA 120 mg, 180 mg, 240 mg, 300 mg, 360 mg, and 420 mg tablets prior to the expiration of the '866 patent.

17. On or about September 19, 2006, Andrx sent a notice letter to Biovail in which Andrx represented that it had filed the Second Amended ANDA No. 77-686 for generic versions of Cardizem® LA 120 mg, 180 mg, 240 mg, 300 mg, 360 mg, and 420 mg tablets, and that it sought approval of its Second Amended ANDA prior to the expiration of the '866 patent. Biovail received a copy of Andrx's notice letter on or about September 22, 2006.

18. On October 4, 2006, within 45 days of receipt of Andrx's September 19, 2006 notice letter, Biovail filed suit against Andrx in this Court, C.A. No. 06-620, alleging that Andrx's filing of its Second Amended ANDA No. 77-686 constituted an act of patent infringement pursuant to 35 U.S.C. § 271(e)(2) and that the commercial manufacture, use, sale, offer for sale and/or importation of Andrx's proposed Second Amended ANDA products would infringe one or more claims of the '866 patent.

19. This Court consolidated C.A. Nos. 05-586, 05-730 and 06-620 by Order dated October 17, 2006 (D.I. 96).

20. The inventions of the '791 patent were conceived and reduced to practice at least as early as June 26, 1991.

21. The inventions of the '866 patent were conceived and reduced to practice at least as early as May 8, 2000.

22. Biovail has asserted that Andrx infringes Claims 1 and 2 of the '791 patent, and Claims 1, 2, 4-6, 39-44, 65, 86, and 88 of the '866 patent.

23. United States Patent No. 4,808,413 ("the '413 patent") to Joshi, et al., qualifies as a prior art reference to the '791 patent under Section 102 of the Patent Act, 35 U.S.C. § 102.

24. United States Patent No. 4,894,240 ("the '240 patent") to Geoghegan, et al., qualifies as a prior art reference to the '791 patent under Section 102 of the Patent Act, 35 U.S.C. § 102.

25. United States Patent No. 4,960,596 ("the '596 patent") to Debregeas, et al., qualifies as a prior art reference to the '791 patent under Section 102 of the Patent Act, 35 U.S.C. § 102.

26. European Patent Application No. 0 320 097 A1 ("the '097 application") to Geoghegan, et al., qualifies as a prior art reference to the '791 patent under Section 102 of the Patent Act, 35 U.S.C. § 102.

27. The Cardizem CD capsule qualifies as a prior art reference to the '866 patent under Section 102 of the Patent Act, 35 U.S.C. § 102.

EXHIBIT 2

EXHIBIT 2 TO PRETRIAL ORDER

PLAINTIFF BIOVAIL'S STATEMENT OF CONTESTED FACTUAL AND LEGAL ISSUES

Plaintiff Biovail submits herein its statement of contested factual and legal issues. To the extent that any issue of fact is deemed to be an issue of law it should be so considered, and to the extent that any issue of law is deemed to be an issue of fact it should be so considered.

U.S. PATENT NO. 5,529,791

I. INFRINGEMENT

Contested Factual Issues

1. Whether Andrx has infringed Claim 1 of U.S. Patent No. 5,529,791 ("'791 patent")?

2. Whether Andrx has infringed Claim 2 of the '791 patent?

II. ANTICIPATION

Contested Factual Issues

1. Whether Andrx has proven by clear and convincing evidence that U.S. Patent No. 4,808,413 ("Joshi '413 patent") renders Claims 1 or 2 of the '791 patent invalid due to anticipation pursuant to 35 U.S.C. § 102?

2. Whether Andrx has proven by clear and convincing evidence that U.S. Patent No. 4,960,596 ("Debregeas '596 patent") renders Claims 1 or 2 of the '791 patent invalid due to anticipation pursuant to 35 U.S.C. § 102?

3. Whether Andrx has proven by clear and convincing evidence that U.S. Patent No. 4,894,240 ("Geoghegan '240 patent") renders Claims 1 or 2 of the '791 patent invalid due to anticipation pursuant to 35 U.S.C. § 102?

4. Whether Andrx has proven by clear and convincing evidence that European Application No. 0 320 097 A1 ("Geoghegan '097 application") renders Claims 1 or 2 of the '791 patent invalid due to anticipation pursuant to 35 U.S.C. § 102?

5. Whether each and every element of Claims 1 and 2 of the '791 patent is disclosed, either expressly or inherently, in the Joshi '413 patent?

6. Whether each and every element of Claims 1 and 2 of the '791 patent is disclosed, either expressly or inherently, in the Debregeas '596 patent?

7. Whether each and every element of Claims 1 and 2 of the '791 patent is disclosed, either expressly or inherently, in the Geoghegan '240 patent?

8. Whether each and every element of Claims 1 and 2 of the '791 patent is disclosed, either expressly or inherently, in the Geoghegan '097 application?

III. OBVIOUSNESS

Contested Legal Issues

1. Whether Andrx has proven by clear and convincing evidence that the differences between the subject matter of Claim 1 of the '791 patent and the asserted prior art are such that the subject matter as a whole of Claim 1 would have been obvious to a person of ordinary skill in the art?

2. Whether Andrx has proven by clear and convincing evidence that the differences between the subject matter of Claim 2 of the '791 patent and the asserted prior art are such that the subject matter as a whole of Claim 2 would have been obvious to a person of ordinary skill in the art?

Contested Factual Issues

1. What is the level of ordinary skill in the art as it pertains to the '791 patent?

2. What is the scope and content of the asserted prior art (Joshi '413 patent, Debregeas '596 patent, Geoghegan '240 patent, and Geoghegan '097 application) as it pertains to Claims 1 and 2 of the '791 patent?

3. What are the differences between Claims 1 and 2 of the '791 patent and the asserted prior art?

4. Would a person of ordinary skill in the art have been motivated to combine the teachings of the Joshi '413 patent, the Debregeas '596 patent, the Geoghegan '240 patent, and/or the Geoghegan '097 application to achieve the inventions of Claims 1 and 2 of the '791 patent?

5. Would a person of ordinary skill in the art expect a likelihood of success in combining the asserted prior art references?

6. What secondary considerations of non-obviousness exist with respect to the inventions claimed in Claims 1 and 2 of the '791 patent?

7. Whether the commercial embodiments of the '791 patent (Cardizem® LA and Tiazac®) have been a commercial success?

8. Whether Cardizem® LA has fulfilled a long-felt need in effective management of hypertension?

9. Whether others failed to develop an effective and consistent once-a-day diltiazem product?

10. Whether there is a nexus between any evidence of secondary considerations of non-obviousness and Claims 1 and 2 of the '791 patent?

11. Whether the commercial embodiments of the '791 patent (Cardizem® LA and Tiazac®) possess unexpected properties in comparison with prior marketed once-a-day diltiazem products?

IV. COLLATERAL ESTOPPEL

Contested Legal Issues

1. Whether Biovail is collaterally estopped from asserting that Andrx's proposed generic versions of Cardizem® LA infringe the '791 patent?

Contested Factual Issues

1. Whether the alleged infringing tablet products are identical to the asserted capsule products of the prior litigation between Biovail and Andrx in the U.S. District Court for the Southern District of Florida, case no. 98-7096 (the "Florida action")?

2. Whether the issues in this action were fairly and fully litigated in the Florida action?

3. What are the differences between the alleged infringing tablet products and the asserted capsule products of the prior litigation between Biovail and Andrx?

V. RELIEF

Contested Legal Issues

1. Whether Biovail is entitled, under 35 U.S.C. § 271(e)(4)(A), to an order that the effective date of any approval of any proposed products under Andrx's ANDA No. 77-686 be a date that is not earlier than the expiration

date for the '791 patent, or any later date of exclusivity to which Biovail is or becomes entitled?

2. Whether Biovail is entitled, under 35 U.S.C. § 271(e)(4)(B), to a permanent injunction, restraining and enjoining Andrx from engaging in the commercial manufacture, use, offer for sale, or sale of its proposed products within the United States, or importation into the United States?

VI. ATTORNEY FEES

Contested Legal Issues

1. Whether this case is exceptional such that Biovail is entitled to attorney fees?

U.S. PATENT NO. 7,108,866

I. INFRINGEMENT

Contested Factual Issues

1. Whether Andrx has infringed Claim 1 of U.S. Patent No. 7,108,866 ("'866 patent")?

2. Whether Andrx has infringed Claim 2 of the '866 patent?

3. Whether Andrx has infringed Claim 4 of the '866 patent?

4. Whether Andrx has infringed Claim 5 of the '866 patent?

5. Whether Andrx has infringed Claim 6 of the '866 patent?

6. Whether Andrx has infringed Claim 65 of the '866 patent?

7. Whether Andrx has infringed Claim 86 of the '866 patent?

8. Whether Andrx has infringed Claim 88 of the '866 patent?

II. ENFORCEABILITY

Contested Legal Issues

1. Whether Andrx has proven by clear and convincing evidence that Edith Mathiowitz, Ph.D., or Robin Teskin, Esq., knowingly failed to disclose material, non-cumulative information, or submitted material false or misleading information to the PTO with the intent of deceiving the PTO?

Contested Factual Issues

1. Does the affidavit of Edith Mathiowitz, Ph.D. ("Mathiowitz affidavit"), which was submitted to the PTO during the prosecution of the '866 patent, contain any material false or misleading statements and/or omissions?

2. If the Mathiowitz affidavit contained any material false or misleading statements and/or omissions, did anyone involved in the submission of the Mathiowitz affidavit to the PTO know that the affidavit contained material false or misleading statements and/or omissions?

3. Did anyone involved in the submission of the Mathiowitz affidavit to the PTO intend to deceive the PTO?

4. Did Biovail's patent attorney, Robin Teskin, Esq., submit any material false or misleading information or fail to disclose material, non-cumulative information to the PTO during the prosecution of the '866 patent?

5. If Robin Teskin submitted any material false or misleading information to the PTO or failed to disclose material, non-cumulative information to the PTO during the prosecution of the '866 patent, did anyone involved in the submission of such information to the PTO know that the information contained material false or misleading statements and/or omissions?

6. Did anyone involved in the submission of information to the PTO through Robin Teskin intend to deceive the PTO?

III. RELIEF

Contested Legal Issues

1. Whether Biovail is entitled, under 35 U.S.C. § 271(e)(4)(A), to an order that the effective date of any approval of any proposed products under Andrx's ANDA No. 77-686 be a date that is not earlier than the expiration date for the '866 patent, or any later date of exclusivity to which Biovail is or becomes entitled?

2. Whether Biovail is entitled, under 35 U.S.C. § 271(e)(4)(B), to a permanent injunction, restraining and enjoining Andrx from engaging in the commercial manufacture, use, offer for sale, or sale of its proposed products within the United States, or importation into the United States?

IV. ATTORNEY FEES

Contested Legal Issues

1. Whether this case is exceptional such that Biovail is entitled to attorney fees?

2. Whether Andrx's inequitable conduct allegations are so facially baseless to warrant an award of attorney fees?

EXHIBIT 3

EXHIBIT 3 TO PRETRIAL ORDER

DEFENDANT ANDRX'S STATEMENT OF
CONTESTED FACTUAL AND LEGAL ISSUES

Defendant Andrx submits herein its statement of contested factual and legal issues. To the extent that any issue of fact is deemed to be an issue of law it should be so considered, and to the extent that any issue of law is deemed to be an issue of fact it should be so considered.

U.S. PATENT NO. 5,529,791

I. INFRINGEMENT

Contested Factual Issues

1. Whether Andrx's proposed diltiazem tablet product of ANDA No. 77-686 literally infringes Claim 1 of U.S. Patent No. 5,529,791 ("'791 patent")?

2. Whether Andrx's proposed diltiazem tablet product of ANDA No. 77-686 literally infringes Claim 2 of the '791 patent?

II. ANTICIPATION

Contested Legal Issues

1. Whether Andrx has proven by clear and convincing evidence that U.S. Patent No. 4,808,413 ("Joshi '413 patent") renders Claims 1 or 2 of the '791 patent invalid due to anticipation pursuant to 35 U.S.C. § 102?

2. Whether Andrx has proven by clear and convincing evidence that U.S. Patent No. 4,960,596 ("Debregeas '596 patent") renders Claims 1 or 2 of the '791 patent invalid due to anticipation pursuant to 35 U.S.C. § 102?

3. Whether Andrx has proven by clear and convincing evidence that U.S. Patent No. 4,894,240 ("Geoghegan '240 patent") renders Claims 1 or 2 of the '791 patent invalid due to anticipation pursuant to 35 U.S.C. § 102?

4. Whether Andrx has proven by clear and convincing evidence that European Application No. 0 320 097 ("Geoghegan '097 application") renders Claims 1 or 2 of the '791 patent invalid due to anticipation pursuant to 35 U.S.C. § 102?

Contested Factual Issues

1. Whether each and every element of Claims 1 and 2 of the '791 patent is disclosed, either expressly or inherently, in the Joshi '413 patent?

2. Whether each and every element of Claims 1 and 2 of the '791 patent is disclosed, either expressly or inherently, in the Debregeas '596 patent?

3. Whether each and every element of Claims 1 and 2 of the '791 patent is disclosed, either expressly or inherently, in the Geoghegan '240 patent?

4. Whether each and every element of Claims 1 and 2 of the '791 patent is disclosed, either expressly or inherently, in the Geoghegan '097 application?

III. OBVIOUSNESS

Contested Legal Issues

1. Whether Andrx has proven by clear and convincing evidence that the differences between the subject matter of Claim 1 of the '791 patent and the asserted prior art are such that the subject matter as a whole of Claim 1 would have been obvious to a person of ordinary skill in the art?

2. Whether Andrx has proven by clear and convincing evidence that the differences between the subject matter of Claim 2 of the '791 patent and the asserted prior art are such that the subject matter as a whole of Claim 2 would have been obvious to a person of ordinary skill in the art?

Contested Factual Issues

1. What is the level of ordinary skill in the art as it pertains to the '791 patent?

2. What is the scope and content of the asserted prior art (Joshi '413 patent, Debregeas '596 patent, Geoghegan '240 patent, and Geoghegan '097 application) as it pertains to claims 1 and 2 of the '791 patent?

3. What are the differences between claims 1 and 2 of the '791 patent and the asserted prior art?

4. Was there a reason that would have prompted a person of ordinary skill in the art to combine the teachings of the asserted prior art to achieve the inventions of claims 1 and 2 of the '791 patent?

5. Did there exist at the time of the invention a known problem for which there was a solution encompassed by the patent's claims?

8. Would a person of ordinary skill in the art have had a reasonable expectation of success in combining the teachings of the asserted prior art?

9. Would a person of ordinary skill in the art have had reason to attempt to make the inventions of claims 1 and 2?

3. Would a person of ordinary skill in the art have been motivated to combine the teachings of the Joshi '413 patent, the Debregeas '596 patent, the Geoghegan '240 patent, and/or the Geoghegan '097 application to achieve the inventions of claims 1 and 2 of the '791 patent?

4. What secondary considerations of non-obviousness exist with respect to the inventions claimed in Claims 1 and 2 of the '791 patent?

5. Whether there is a nexus between any evidence of secondary considerations of non-obviousness and Claims 1 and 2 of the '791 patent?

IV. ESTOPPEL

Contested Legal Issues

1. Whether Biovail is collaterally estopped from asserting that Andrx's proposed generic versions of Cardizem® LA infringe the '791 patent?

2. Whether Biovail is estopped from asserting that the sugar core seed structure of Andrx's product infringes, by virtue of Biovail's amendment of claims and arguments to the PTO in order to overcome rejections based on the sugar core seed structure of the bead in the Debregeas '596 patent?

Contested Factual Issues

1. Whether the issue at stake is identical to the one involved in the prior litigation between Biovail and Andrx in the U.S. District Court for the Southern District of Florida, case no. 98-7096 ("Florida action")?

2. Whether the issue at stake was actually litigated in the prior action?

3. Whether the determination of the issue in the prior suit was a critical and necessary part of the judgment in that action?

4. Whether the party against whom the earlier decision is asserted had a full and fair opportunity to litigate the issue in the earlier proceeding?

5. Whether the applicants unambiguously distinguished the claimed invention from the sugar core seed structure taught by Debregeas and practiced by Andrx in the accused tablet, so that the public was entitled to rely on the applicants' statements in designing around the patent by practicing the prior art sugar core seed structure?

V. RELIEF

Contested Legal Issues

1. Whether Biovail is entitled, under 35 U.S.C. § 271(e)(4)(A), to an order that the effective date of any approval of any proposed products under Andrx's ANDA No. 77-686 be a date that is not earlier than the expiration date for the '791 patent, or any later date of exclusivity to which Biovail is or becomes entitled?

2. Whether Biovail is entitled, under 35 U.S.C. § 271(e)(4)(B), to a permanent injunction, restraining and enjoining Andrx from engaging in the commercial manufacture, use, offer for sale, or sale of its proposed products within the United States, or importation into the United States?

3. Whether Andrx is entitled to a judgment declaring that its proposed diltiazem tablet product of ANDA No. 77-686 does not infringe the asserted claims of the '791 patent.

4. Whether Andrx is entitled to a judgment declaring that the '791 patent is invalid in light of the prior art.

VI. ATTORNEY FEES

Contested Legal Issues

1. Whether this case is exceptional such that Andrx is entitled to attorney fees?

2. Whether this case is exceptional such that Biovail is entitled to attorney fees?

U.S. PATENT NO. 7,108,866

I. INFRINGEMENT

Contested Factual Issues

1. Whether Andrx has infringed Claim 1 of U.S. Patent No. 7,108,866 ("'866 patent")?

2. Whether Andrx has infringed Claim 2 of the '866 patent?

3. Whether Andrx has infringed Claim 4 of the '866 patent?

4. Whether Andrx has infringed Claim 5 of the '866 patent?

5. Whether Andrx has infringed Claim 6 of the '866 patent?

6. Whether Andrx has infringed Claim 65 of the '866 patent?

7. Whether Andrx has infringed Claim 86 of the '866 patent?

8. Whether Andrx has infringed Claim 88 of the '866 patent?

II. ENFORCEABILITY

Contested Legal Issues

1. Whether Andrx has proven by clear and convincing evidence that Biovail, Edith Mathiowitz, Ph.D., Robin Teskin, Esq., or anyone at Biovail involved with the prosecution knowingly failed to disclose material, non-cumulative information, or submitted material false or misleading information to the PTO with the intent of deceiving the PTO?

Contested Factual Issues

1. Does the affidavit of Edith Mathiowitz, Ph.D. ("Mathiowitz affidavit"), which was submitted to the PTO during the prosecution of the '866 patent, contain any material false or misleading statements and/or omissions?

2. If the Mathiowitz affidavit contained any material false or misleading statements and/or omissions, did anyone involved in the submission of the Mathiowitz affidavit to the PTO know or should they have known that the affidavit contained material false or misleading statements and/or omissions?

3. Did anyone involved in the submission of the Mathiowitz affidavit to the PTO intend to deceive the PTO?

4. Did Biovail's patent attorney, Robin Teskin, Esq., submit any material false or misleading information or fail to disclose material information to the PTO during the prosecution of the '866 patent?

5. If Robin Teskin submitted any material false or misleading information to the PTO or failed to disclose material information to the PTO during the prosecution of the '866 patent, did anyone involved in the submission of such information to the PTO know or should they have known that the information contained material false or misleading statements and/or that the omitted information was material?

6. Did anyone involved in the submission of information to the PTO through Robin Teskin intend to deceive the PTO?

III. RELIEF

Contested Legal Issues

1. Whether Biovail is entitled, under 35 U.S.C. § 271(e)(4)(A), to an order that the effective date of any approval of any proposed products under Andrx's ANDA No. 77-686 be a date that is not earlier than the expiration date for the '866 patent, or any later date of exclusivity to which Biovail is or becomes entitled?

2. Whether Biovail is entitled, under 35 U.S.C. § 271(e)(4)(B), to a permanent injunction, restraining and enjoining Andrx from engaging in the commercial manufacture, use, offer for sale, or sale of its proposed products within the United States, or importation into the United States?

3. Whether Andrx is entitled to a judgment declaring that its proposed diltiazem tablet product of ANDA No. 77-686 does not infringe the asserted claims of the '866 patent.

4. Whether Andrx is entitled to a judgment declaring that the '866 patent is unenforceable due to inequitable conduct.

IV. ATTORNEY FEES

Contested Legal Issues

1. Whether this case is exceptional such that Andrx is entitled to attorney fees?

2. Whether this case is exceptional such that Biovail is entitled to attorney fees?

EXHIBIT 4

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LIST OF PLAINTIFF'S TRIAL EXHIBITS

Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
1	Certified U.S. Patent No. 5,529,791				
2	Certified U.S. Patent No. 7,108,866				
3	U.S. Patent No. 5,288,505			NPI	
4	U.S. Patent Publication No. 20070036856 A1			NPI	
5	File History of U.S. Patent No. 5,529,791			NPI, A	

R = Relevance (Rule 402 and/or 403)
W = Relevance outweighed by prejudice, waste or confusion (Rule 403)
H = Hearsay (Rules 801-802)
MD = Multiple documents. Further objections reserved pending identification of each specific document Biovail seeks to introduce.
NP/A = No indication of document having been produced in this case until after service of proposed exhibit list and/or authentication (Rule 901(a)).
NPI = Not properly identified. All objections reserved until inspection of document.
F = Lack of Foundation
DU = Duplicative
C = Incomplete document. Further objections reserved pending Biovail provision of full document.
A = Lack of authentication (Rule 901 (a)).

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LIST OF PLAINTIFF'S TRIAL EXHIBITS

Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
6	File History of U.S. Patent No. 7,108,866			NPI	
7	April 10, 2005 Affidavit of Edith Mathiowitz, Ph.D.			NPI, NP/A, Provided too late to reconcile discrepancies	
8	June 22, 2005 Andrx Notice Letter to Biovail			W, NPI	
9	August 30, 2005 Notice Letter to Biovail			W, NPI	
10	September 19, 2006 Notice Letter to Biovail			W, NPI	
11	EXHIBIT REMOVED				
12	Curriculum Vitae of G.S. Brenner, Ph.D.			H	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
13	Curriculum Vitae of T.S. Foster, Pharm.D.			H	
14	Curriculum Vitae of J.M. Neutel, M.D.			H	
15	Curriculum Vitae of M.C. Davies, Ph.D.			H	
16	Curriculum Vitae of R.A. Bodmeier, Ph.D.			H	
17	Curriculum Vitae of S.M. Bolton, Ph.D.			H, R	
18	Curriculum Vitae of M.C. Meyer, Ph.D.			H	
19	Curriculum Vitae of T.M. Niemczyk, Ph.D.			H	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
20	Curriculum Vitae of S.C. Porter, Ph.D.			H, R	
21	Curriculum Vitae of N. Weiner, Ph.D.			H, R	
22	Curriculum Vitae of C.Y. Wu, Ph.D.			H	
23	Curriculum Vitae of E. Mathiowitz, Ph.D.			H, R, NPI	
24	Curriculum Vitae of A. M. Deboeck			H, R, NPI	
25	Product Development Report for the Diltiazem HCL Extended Release Bead Tablet	BLS 009754 – 009771		R	
26	Product Development Report for the Diltiazem HCl Extended Release Bead Coated Tablets	BLS 009843 – BLS 009933		R	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
27	Wax Placebo Bead Development Report	BLS 009934 – BLS 009996		R	
28	Memorandum dated 10/02/03, from G. Butler to J. Miszuk, re Biovail/Galephar Agreements	BLS 026166 – BLS 026223		R	
29	EXHIBIT REMOVED				
30	Agreement (December 15, 1998)	B012253 – B012267		R, NP/A, NPI	
31	Andrx ANDA # 77-686 Book 1 of 38	ANDCLA 00001 – ANDCLA 00511		MD, R (as to ANDCLA 0061-139)	
32	Andrx ANDA # 77-686 Book 2 of 38	ANDCLA 00512 – ANDCLA 01035		MD, W	
33	Andrx ANDA # 77-686 Book 3 of 38	ANDCLA 01036 – ANDCLA 01377		MD, R	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
34	Andrx ANDA # 77-686 Book 4 of 38	ANDCLA 01378 – ANDCLA 01779		MD, R	
35	Andrx ANDA # 77-686 Book 5 of 38	ANDCLA 01780 – ANDCLA 02181		MD, R	
36	Andrx ANDA # 77-686 Book 6 of 38	ANDCLA 02182 – ANDCLA 02529		MD, R	
37	Andrx ANDA # 77-686 Book 7 of 38	ANDCLA 02530 – ANDCLA 02875		MD, R	
38	Andrx ANDA # 77-686 Book 8 of 38	ANDCLA 02876 – ANDCLA 03221		MD, R	
39	Andrx ANDA # 77-686 Book 9 of 38	ANDCLA 03222 – ANDCLA 03568		MD, R	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
40	Andrx ANDA # 77-686 Book 10 of 38	ANDCLA 03569 – ANDCLA 03915		MD, R	
41	Andrx ANDA # 77-686 Book 11 of 38	ANDCLA 03916 – ANDCLA 04261		MD, R	
42	Andrx ANDA # 77-686 Book 12 of 38	ANDCLA 04262 – ANDCLA 04608		MD, R	
43	Andrx ANDA # 77-686 Book 13 of 38	ANDCLA 04609 – ANDCLA 04920		MD, R	
44	Andrx ANDA # 77-686 Book 14 of 38	ANDCLA 04921 – ANDCLA 05323		MD, R	
45	Andrx ANDA # 77-686 Book 15 of 38	ANDCLA 05324 – ANDCLA 05693		MD, R	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
46	Andrx ANDA # 77-686 Book 16 of 38	ANDCLA 05694 – ANDCLA 06010		MD, R	
47	Andrx ANDA # 77-686 Book 17 of 38	ANDCLA 06011 – ANDCLA 06407		MD, R	
48	Andrx ANDA # 77-686 Book 18 of 38	ANDCLA 06408 – ANDCLA 06807		MD, R	
49	Andrx ANDA # 77-686 Book 19 of 38	ANDCLA 06808 – ANDCLA 07209		MD, R	
50	Andrx ANDA # 77-686 Book 20 of 38	ANDCLA 07210 – ANDCLA 07623		MD, R	
51	Andrx ANDA # 77-686 Book 21 of 38	ANDCLA 07624 – ANDCLA 07957		MD, R	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
52	Andrx ANDA # 77-686 Book 22 of 38	ANDCLA 07958 – ANDCLA 08242		MD, R	
53	Andrx ANDA # 77-686 Book 23 of 38	ANDCLA 08243 – ANDCLA 08652		MD, R	
54	Andrx ANDA # 77-686 Book 24 of 38	ANDCLA 08653 – ANDCLA 08908		MD, R	
55	Andrx ANDA # 77-686 Book 25 of 38	ANDCLA 08909 – ANDCLA 09295		MD, R	
56	Andrx ANDA # 77-686 Book 26 of 38	ANDCLA 09296 – ANDCLA 09641		MD, R	
57	Andrx ANDA # 77-686 Book 27 of 38	ANDCLA 09642 – ANDCLA 09988		MD, R	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
58	Andrx ANDA # 77-686 Book 28 of 38	ANDCLA 09989 – ANDCLA 10335		MD, R	
59	Andrx ANDA # 77-686 Book 29 of 38	ANDCLA 10336 – ANDCLA 10852		MD, R	
60	Andrx ANDA # 77-686 Book 30 of 38	ANDCLA 10853 – ANDCLA 11198		MD, R	
61	Andrx ANDA # 77-686 Book 31 of 38	ANDCLA 11199 – ANDCLA 11637		MD, R	
62	Andrx ANDA # 77-686 Book 32 of 38	ANDCLA 11638 – ANDCLA 11951		MD, R	
63	Andrx ANDA # 77-686 Book 33 of 38	ANDCLA 11952 – ANDCLA 12283		MD, R	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
64	Andrx ANDA # 77-686 Book 34 of 38	ANDCLA 12284 – ANDCLA 12669		MD, R	
65	Andrx ANDA # 77-686 Book 35 of 38	ANDCLA 12670 – ANDCLA 13008		MD, R	
66	Andrx ANDA # 77-686 Book 36 of 38	ANDCLA 13009 – ANDCLA 13368		MD, R	
67	Andrx ANDA # 77-686 Book 37 of 38	ANDCLA 13369 – ANDCLA 13656		MD, R	
68	Andrx ANDA # 77-686 Book 38 of 38	ANDCLA 13657 – ANDCLA 14011		MD, R	
69	Andrx ANDA # 77-686 Correspondence Book #2	ANDCLA 14012 – ANDCLA 14136		MD, R, H	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
70	Andrx ANDA # 77-686 Correspondence Book #3.1	ANDCLA 14138 – ANDCLA 14541		MD, R (14218-267, 14306-308)	
71	Andrx ANDA # 77-686 Correspondence Book #3.2	ANDCLA 14542 – ANDCLA 14898		MD, W	
72	Andrx ANDA # 77-686 Correspondence Book #3.3	ANDCLA 14899 – ANDCLA 15315		MD, W	
73	Andrx ANDA # 77-686 Correspondence Book #3.4	ANDCLA 15316 – ANDCLA 15912		MD, W	
74	Andrx ANDA # 77-686 Correspondence Book #4	ANDCLA 15913 – ANDCLA 15929		MD, R	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
75	Andrx ANDA # 77-686 Correspondence Book 04/27/06 – 11/01/06	ANDCLA 110903 – ANDCLA 111624		MD, R, H	
76	Andrx ANDA # 77-686 (Compilation Part 1)		Vaughn Dep. Exh. 20A	MD, R, W, F, DU of Px 31 R (as to ANDCLA 00061 – 139)	
77	Andrx ANDA # 77-686 (Compilation Part 2)		Vaughn Dep. Exh. 20B	MD, W, F, DU of Px 31	
78	Andrx ANDA # 77-686 (Compilation Part 3)		Vaughn Dep. Exh. 20C	MD, R, W, F, DU of Px 32	
79	Andrx ANDA # 77-686 (Compilation Part 4)		Vaughn Dep. Exh. 20D	MD, R, W, F, DU of Px 32	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
80	Andrx ANDA # 77-686 (Compilation Part 5)		Vaughn Dep. Exh. 21A	MD, H, R, W, F, DU of Px 70	
81	Andrx ANDA # 77-686 (Compilation Part 6)		Vaughn Dep. Exh. 21B	MD, H, R, W, F, DU of Px 71	
82	Andrx ANDA # 77-686 (Compilation Part 7)		Vaughn Dep. Exh. 21C	MD, H, R, W, F, DU of Px 72	
83	Andrx ANDA # 77-686 (Compilation Part 8)		Vaughn Dep. Exh. 21D	MD, H, R, W, F, DU of Px 72	
84	Andrx ANDA # 77-686 (Compilation Part 9)		Vaughn Dep. Exh. 21E	MD, H, R, W, F, DU of Px 73	
85	Andrx ANDA # 77-686 (Compilation Part 10)		Vaughn Dep. Exh. 21F	MD, H, R, W, F, DU of Px 73	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
86	Andrx ANDA # 77-686 Components and Composition Statements	ANDCLA 00140 – ANDCLA 00144	Jan Dep. Exh. 65		
87	EXHIBIT REMOVED				
88	Andrx ANDA # 77-686 Manufacturing and Process Instructions	ANDCLA 14544 - ANDCLA 14548			
89	Andrx ANDA 77-686 March 29, 2006 Bioequivalency Amendment from FDA		Vaughn Dep. Exh. 25		
90	Andrx ANDA 75-401 Excerpt	ANDCLA 69884 – ANDCLA 70077	Jan. 19, 2007 Brenner Expert Declaration Exhibit 13		

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
91	Andrx ANDA 75-401 Excerpt	ANDCLA 93272 – ANDCLA 93273 ANDCLA 93274 – ANDCLA 93336 ANDCLA 93384 – ANDCLA 93408 ANDCLA 93456 – ANDCLA 93480 ANDCLA 93528 – ANDCLA 93552 ANDCLA 93600 – ANDCLA 93602	Jan. 19, 2007 Brenner Expert Declaration Exhibit 14	MD	
92	Andrx ANDA # 75-401 Components and Compositions Statements	ANDCLA 69636 – ANDCLA 69640			

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
93	Andrx ANDA 75-401 Excerpt	ANDCLA 92843 – ANDCLA 92867	Jan. 19, 2007 Brenner Expert Declaration Exhibit 12		
94	Andrx ANDA # 75-401 Excerpt	9373 - 9375	Jan. 19, 2007 Brenner Expert Declaration Exhibit 15		
95	Andrx ANDA # 75-401 Active Drug Layering – Active Pellets	ANDCLA 69735 – ANDCLA 69883			
96	Andrx ANDA # 75-401 Manufacturing and Processing Instructions	ANDCLA 92870 – ANDCLA 93262			
97	Andrx ANDA # 75-401 Excerpt	ANDCLA 92870	Jan. 19, 2007 Brenner Expert Declaration Exhibit 16		

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
98	Diltiazem Controlled Release Formulation and Method of Manufacture	ANDCLA 22915 – ANDCLA 22963	Jan. 19, 2007 Brenner Expert Declaration Exhibit 19		
99	Andrx ANDA Transmittal Letter	ANDCLA 00002 – ANDCLA 00004	Jan. 19, 2007 Brenner Expert Declaration Exhibit 21		
100	EXHIBIT REMOVED				
101	Letter, undated, from N. Stockbridge (FDA) to N. Islam of Biovail Technologies Ltd.		Bolton Dep. Exh. 159	R, H	
102	March 3, 2004 FDA Inspection Report			R, H	
103	May 17, 2005 FDA Inspection Report			R, H	
104	EXHIBIT REMOVED				

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
105	Letter dated 04/27/06, from J. Vaughn to G. Beuhler enclosing Bioequivalency Amendment	ANDCLA 107049-ANDCLA 107079	Vaughn Dep. Exh. 26		
106	ANDA 77-686 Minor Amendment from FDA (02/10/06)	ANDCLA 103013-ANDCLA 103017	Vaughn Dep. Exh. 27		
107	Inspection Report by FDA (04/18/06)			R, H	
108	FDA Bioequivalency Amendment ANDA 77-686 (10/27/05)	ANDCLA 103086–ANDCLA 103087			
109	Andrx's Labeling Amendment (09/25/06)	ANDCLA 110830-ANDCLA 110900		W	
110	Jan. 5, 2001 Letter from D. Servello (Andrx) to G. Buehler (FDA)	ANDCLA 101440 – ANDCLA 101443		W	
111	Biovail 1996 Annual Report			H, R	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
112	Biovail 1997 Annual Report			H, R	
113	Biovail 1998 Annual Report			H, R, NP/A	
114	Biovail 1999 Annual Report			H, R, NP/A	
115	Biovail 2000 Annual Report			H, R, NP/A	
116	Biovail 2001 Annual Report			H, R, NP/A	
117	Biovail 2002 Annual Report			H, R, NP/A	
118	Biovail 2003 Annual Report			H, R, NP/A	
119	Biovail 2004 Annual Report			H, R, NP/A	
120	Biovail 2005 Annual Report			H, R	
121	Biovail 2006 Annual Report			H, R, NP/A	
122	July 8, 2002 Andrx Press Release		Rosenthal Dep. Exh. 57	H, R	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
123	Andrx Corp. 2003 Annual Report			R, NP/A	
124	Sept. 8, 2004 Andrx Press Release		Rosenthal Dep. Exh. 62	R	
125	Andrx Corp. 2004 Annual Report			R, NP/A	
126	July 29, 2005 Q2 2005 Andrx Corporation Earnings Conference Call Transcript			H, R, F, NP/A	
127	Andrx Aug. 4, 2005 Form 10-Q (period: June 30, 2005)			R, NP/A	
128	Sept. 6, 2005 Andrx Press Release			R, NP/A	
129	Nov. 8, 2005 Q3 2005 Andrx Corporation Earnings Conference Call Transcript			H, R, F, NP/A	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
130	Singer, G., Andrx prepares for session with FDA, South Florida Sun-Sentinel, Broward Metro Edition, Dec. 11, 2005, pgs. 1E, 4E			H, R, NP/A	
131	Andrx Dec. 15, 2005 Form 8-K (period: Dec. 14, 2005)			R, NP/A	
132	Singer, G., Lead Plaintiff set in lawsuit against drug maker Andrx Corp., South Florida Sun-Sentinel, Broward Metro Edition, Feb. 1, 2006, pg. 3D			H, R, NP/A	
133	Andrx March 13, 2006 Form 8-K (period: March 12, 2006)			R, NP/A	
134	Andrx March 13, 2006 Form 8-K (period: March 13, 2006)			R, NP/A	
135	Andrx March 13, 2006 Form DEFA14A			R, NP/A	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
136	Andrx March 16, 2006 Form 10-K (period: Dec. 31, 2005)			R, NP/A	
137	April 18, 2006 FDA Form 483			R, H, NP/A	
138	April 19, 2006 Form 8-K (period: April 18, 2006)			R, NP/A	
139	Singer, G., FDA finds dozens new manufacturing deficiencies at Andrx, South Florida Sun-Sentinel, Broward Metro Edition, April 25, 2006, pg. 1.D			R, H, NP/A	
140	Andrx May 1, 2006 Amended Form 10-K (period: Dec.31, 2005)			R, NP/A	
141	Andrx May 4, 2006 Form 10-Q (period: March 31, 2006)			R, NP/A	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
142	May 5, 2005 Q1 2005 Andrx Corporation Earnings Conference Call Transcript			R, H, NP/A	
143	Andrx Aug. 8, 2006 Form 10-Q (period: June 30, 2006)			R, NP/A	
144	Andrx Sep. 13, 2006 Form 8-K (period: Sep. 13, 2006)			R, NP/A	
145	EXHIBIT REMOVED				
146	Exhibit 99.1 to Andrx's Sep. 13, 2006 8k			R, NP/A	
147	Watson Pharmaceuticals, Inc. Nov. 7, 2006 Form 10-Q			R, NP/A	
148	Aug. 2, 2007 Q2 2007 Watson Pharmaceuticals, Inc. Earnings Conference Call Transcript			R, H, NP/A, F	

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149	Andrx ANDA # 77-686 Excerpt	ANDCLA 14197 – ANDCLA 14216	Jan. 19, 2007 Brenner Declaration Exhibit 6 (part 2)	R	
150	EXHIBIT REMOVED				
151	EXHIBIT REMOVED				
152	Biovail Study # 2293	BLS 053097 – BLS 053371		R	
153	EXHIBIT REMOVED				
154	Biovail Study # 2370	BLS 019146 – BLS 019281		R	
155	Biovail Study # 2434	BLS 019849 – BLS 019913		R	
156	Biovail Study # 2435	BLS 019641 – BLS 019724		R	

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157	Biovail Study # 2464	BLS 020384 – BLS 020428		R	
158	Biovail Study # 2489	BLS 019551 – BLS 019616		R	
159	Biovail Study # 2492	BLS 019748 – BLS 019825		R	
160	Biovail Study # 2463	BLS 019938 – BLS 020023		R	
161	Andrx Study # R04-1764	ANDCLA 01042 – ANDCLA 01129		R	
162	Andrx Study # R04-1765	ANDCLA 07630 – ANDCLA 07715		R	
163	Letter, dated 01/12/06, by P. Ratliff re Pharmaceutical Product Samples to M. Davies	BLS 070140 – BLS 070142			

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164	Letter, dated 01/12/06, by P. Ratliff re Pharmaceutical Product Samples to M. Davies	BLS 070143 – BLS 070145			
165	Letter, dated 04/15/06, by P. Ratliff re Pharmaceutical Product Samples to M. Davies enclosing Packing Slip of Samples and Pro Forma Commercial Invoice (18 items)	BLS 070146 – BLS 070148			
166	Laboratory Notebook	BLS 026700 – BLS 026743		H, F, C	
167	Laboratory Notebook	BLS 026745 – BLS 026758		H, F, C	
168	Davies Hard Disk Drive	BLS 026759		H, R, MD, F	
169	Andrx's Jan. 3, 2006 Response to Biovail's First Set of Interrogatories			W	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
170	Biovail's March 9, 2006 Rule 30(b)(6) Notice to Andrx		Vaughn Dep. Exh. 18	W	
171	March 31, 2006 Letter from D. Carsten to P. Ratliff		Vaughn Dep. Exh. 19	W	
172	October 23, 2006 Revised Notice of Subpoena		Copa Dep. Exh. 135	W	
173	Andrx's Jan. 3, 2006 Response to Biovail's First Set of Interrogatories			W, DU	
174	Andrx's Nov. 16, 2006 Response to Biovail's First Set of Interrogatories			W	
175	Biovail's May 14, 2007 Interrogatories to Andrx relating to the issue of Inequitable Conduct			R	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
176	Andrx's Nov. 18, 2005 Initial Disclosures			W	
177	Eradiri, O., et al., Comparison of diltiazem bioavailability from 3 marketed extended-release products for once-daily administration: implications of chronopharmacokinetics and dynamics, *Int'l J. of Clin. Pharmacology and Therapeutics*, Vol. 35, No. 9, (1997), pp.: 369 - 373	BLS 030937 – BLS 030941		H	
178	Thiffault, J., et al., The Influence of Time of Administration on the Pharmacokinetics of a Once-a-Day Diltiazem Formulation: Morning Against Bedtime, *Biopharmaceutics and Drug Disposition*, Vol. 17, pp.107-115 (1996)			H	

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179	FDA Guidance for Industry re Bioavailability and Bioequivalence Studies for Orally Administered Drugs Products – General Considerations (Revision I – March 2003)			R	
180	U.S. Patent No. 4,832,958			R, NP/A	
181	U.S. Patent No. 4,859,469			R, NP/A	
182	FDA Guidance for Industry re Oral Extended (Controlled) Release Dosage Forms *in vivo* Bioequivalence and *in vitro* Dissolution Testing			NPI	
183	EXHIBIT REMOVED				

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
184	Niemczyk Power Point Presentation: Quantitative Analysis of Polymorphic Mixtures using Infrared Spectroscopy		Niemczyk Dep. Exh. 177	H	
185	Qiu, Yihong, and Zhang, Guohua, Research and Development Aspects of Oral Controlled-Release Dosage Forms, in *Handbook of Pharmaceutical Controlled Release Technology*, Wise, Donald L. (ed.), Marcel Dekker, Inc. New York		Zhang Dep. Exh. 92	H, R	
186	R. Turton and X.X. Cheng, The Scale-Up of Spray Coating Processes for Granular Solids and Tablets, *Powder Technology*, 150 (2005) 78-85		Cheng Dep. Exh. 107	H, R	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
187	Streubel, A., et al., pH-independent Release of a Weakly Basic Drug from Water-Insoluble and –soluble Matrix Tablets, J. of Controlled Release, Vol. 67 (2000), pp. 101-110			H, R	
188	M. Meyer, K. Chan, and S. Bolton, "Generic Warfarin: Implications for Patient Care – Another View", Pharmacotherapy, Vol. 18, No. 4 (1998), pp. 884-886.			H, R, NP/A	
189	Suleiman, M., et al., Stability of Diltiazem Hydrochloride in aqueous sugar solutions, *J. Clin. Pharmacy and Therapeutics*, (1988) Vol. 13, pp.: 417 – 422		Maes Dep. Exh. 42	H, NP/A	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
190	Sista, S., et.al., Pharmacokinetics of a Novel Dilitiazem HCL Extended-Release Tablet Formulation for Evening Administration, *J. Clin Pharmacol* 2003;43:1149-1157			H, NP/A	
191	Glasser, S. P., Neutel, J.M., Gana, T. I. and Albert, K.S., Efficacy and Safety of a Once Daily Graded-Release Diltiazem Formulation in Essential Hypertension, *Am. J. of Hypertension*, Vol. XVI (2003), pp. 51 - 58			H, NP/A	
192	Wright, J.T., et.al., Antihypertensive Efficacy of Night-time Graded-Release Diltiazem Versus Morning Amlodipine in African Americans, *Am. J. of Hypertension*, Vol. 17 (2004), pp.: 734-742	BLS 023268 – BLS 023278		H, NP/A	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
193	White, W. B., et.al., Effects of graded-release diltiazem versus ramipril, dosed at bedtime, on early morning blood pressure, heart rate, and the rate-pressure product, *Am. Heart J.*, Vol. 148 No.4 (October 2004), pp.: 628-634			H, NP/A	
194	Glasser, S.P., et.al., Efficacy and safety of a once-daily graded-release diltiazem formulation dosed at bedtime compared to placebo and to morning dosing in chronic stable angina pectoris, *Am. Heart J.* Vol. 149 No.2 (February 2005), pp.: 290.e1 - 290.e9			H, NP/A	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
195	Glasser, S.P., Antihypertensive Safety and Efficacy and Physician and Patient Satisfaction: Results From a Phase 4 Practice-Baded Clinical Experience Trial With Diltiazem LA, *Advances in Therapy*, Vol. 23 No.2 (March/April 2006), pp.:284-294			H, NP/A	
196	Won, C.M., Kinetics of hydrolysis of diltiazem, International Journal of Pharmaceutics, 79 (1992) 183-190			H, NP/A	
197	Janicki, S., et al., Diltiazem Multi-Dose Gastrointestinal Diffusion System: Preparation and Release Rate Studies, Il Farmaco, 44(5), 531-539 (1989)			H, NP/A	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
198	Bodmeier, R. et al., The Influence of Buffer Species and Strength on Diltiazem HCl Release from Beads Coated with the Aqueous Cationic Polymer Dispersions, Eudragit RS, RL 30D, Pharmaceutical Research, Vol. 13, No. 1 (1996)			H, NP/A	
199	Miller, R. A., et al., The Compression of Spheres Coated with an Aqueous Ethylcellulose Dispersion, Drug Development and Industrial Pharmacy, 25(4), 503-511 (1999), pp. 503-511			H, NP/A	
200	Nixon, J.R., et al., The effect of tabletting on the dissolution behaviour of thiabendazole microcapsules, J. Pharm. Pharmacol. 32:857-59 (1980)			H, NP/A	

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201	Vergote, G.J., et al., Wax beads as cushioning agents during the compression of coated diltiazem pellets, European J. of Pharmaceutical Sciences 17:145-151 (2002)			H, NP/A	
202	Smithkline Beecham Corp., et al. v. Apotex Corp., et al., 247 F.Supp.2d 1011 (N.D.Ill. 2003)			R	
203	Diltiazem ER Capsules Product Development Report (09/18/97)	BLS 026482 – BLS 026699			
204	Biovail Development Reports Volume 1 (G99)	BLS 010501 – BLS 010852		R	
205	Biovail Product development Report for the Diltiazem HCl Extended Release Bead Coated Tablets, 120, 180, and 420 mg (02/28/02)	BLS 009849 – BLS 009933		R	

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206	Solubility of Diltiazem in Water and Sucrose Solution	B013998 – B014000		H, F	
207	Rights Agreement between Biovail and Hoechst-Roussel Pharmaceutical Inc. (06/30/93)	ANDCLA 25021-ANDCLA 25043		H, R	
208	EXHIBIT REMOVED				
209	Revenue Chart	BLS 022200		H	
210	Sales Revenue Chart/Expenses	BLS 021059 – BLS 021068		H	
211	Master Formula, Diltiazem HCl ER Pellets (Tiazac), Product Code S212, Lot #: P97018 (01/15/97)	ANDCLA 23104 – ANDCLA 23119			

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212	Monograph, titled "Andrx's Generic Cardizem CD Two-peak Versus One-peak" (Source and author are unknown)	ANDCLA 39323 - ANDCLA 39325		H, R, F, A	
213	Master Formula, Diltiazem HCl ER Pellets (Tiazac), Lot #: P96141 (04/05/96)	ANDCLA 23079 - ANDCLA 23102			
214	Handwritten Calculations by Sanford Bolton		Bolton Dep. Exh. 164	H, R	
215	Skyscan Brochure 2006		www.skyscan.be/next/SkyScan_brochure.pdf	H, R	
216	DataViewer version history		Wu Dep. Exh. 171	H, R	
217	Skyscan Images of Diltiazem ER Pellets		Wu Dep. Exh. 172	H, R	

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218	CT images of Dilitazem		Wu Dep. Exh. 173	H, R	
219	Sept. 9, 1995 Asset Purchase Agreement	ANDCLA 25069 – ANDCLA 25161		H, R	
220	Celphere Brochure		Cheng Dep. Exh. 100	H, R	
221	Revised Package Insert with Side by Side Comparison (06/06)	ANDCLA 110860– ANDCLA 110900	Copa Dep. Exh. 147	R	
222	Chart		Bodmeier Dep. Exh. 193	H	
223	Nov. 11, 2006 Expert Report of Norman Weiner			H, R – witness will not be called	
224	Expert Report of Stuart Porter			H, R – witness will not be called	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
225	C.Y. Wu, B.C. Hancock, A. Mills, A.C. Bentham, S.M. Best, and J.A. Elliott "Numerical and experimental investigation of capping mechanisms during pharmaceutical tablet compaction" Powder Technology via "Particulate Processes in the Pharmaceutical Industry", June 26-30, 2005, pp. 1-19.			H, NP/A	
226	B.C. Hancock and M.P. Mullarney, "X-ray Microtomography of Solid Dosage Forms" Pharmaceutical Technology, April 2005, pp. 92-100.			H, NP/A	
227	W. Huber, A. Bubendorf, A. Grieder, D. Obrecht, "Monitoring solid phase synthesis by infrared spectroscopic techniques" Analytica Chimica Acta 393 (1999) 213-221.			H, NP/A	

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228	J.S. Loring, M. Karlsson, W.R. Fawcett, W.H. Casey, "Infrared spectra of phthalic acid, the hydrogen phthalate ion, and the phthalate ion in aqueous solution" Spectrochimica Acta Part A 57 (2001) 1635-1642			H, NP/A	
229	Thom, T., et al. Heart Disease and Stroke Statistics – 2006 Update, *Circulation*, American Heart Association, 02/14/06, pp. e86-e87			H, NP/A	
230	Cardizem LA Package Insert. Revised 04/04			R, H	
231	Tiazac ER Package Insert. Revised 07/03			R, H	
232	Approved Drug Products ("Orange Book"), 26th Edition, FDA, 2006, pp.31-32			H, R, C	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
233	Smith, D.H.G., Neutel, J.M., and Weber, M.A., Comparisons of the effects of Different Long-Acting Delivery Systems on the Pharmacokinetics and Pharmacodynamics of Diltiazem, *Am. J. of Hypertension*, 1999;12:1030-1037			H, NP/A	
234	Neutel, J.M., et al., Current Challenges in the Management of Hypertension: Effective Single-Dose Monotherapy with a Novel Formulation of Diltiazem, *Advances in Therapy*, Vol. 13, No. 5, September/October 1996	B 007372 – B 007386		H, NP/A	
235	Lacourciere, Y., et al., Clincial Efficacy of Force Titrated Doses of Diltiazem Extended-Release: A Placebo Controlled Study, *Am. J. of Hypertension*, 1995; 8:282-286	B 007391 – B 007395		H, NP/A	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
236	Neutel, J.M., et al., Optimization of Antihypertensive Therapy with a Novel, Extended-Release Formulation of Diltiazem: Results of a Practice-Based Clinical Study, *Clinical Therapeutics*, Vol. 19, No. 6, November/December 1997	B 007356 – B 007371		H, R, NP/A	
237	Smith, D.H.G., and Neutel, J.M., Comparison of the Pharmacodynamic Profiles of Two Different Long-Acting Diltiazem Delivery Systems (Presented at the American Society of Hypertension, 12th Scientific Meeting Exposition May 27-31, 1997, San Francisco, CA)			H, R, NP/A	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
238	Glasser, S. P., Neutel, J.M., Gana, T. I. and Albert, K.S., Efficacy and Safety of a Once Daily Graded-Release Diltiazem Formulation in Essential Hypertension, *Am. J. of Hypertension*, Vol. XVI (2003), pp. 51 - 58			H, R, NP/A	
239	Communication to the USPTO Office Action mailed 10/11/00 in re U.S. Patent Application No. 09/465,338				
240	Communication from the USPTO Office Action mailed 02/21/02 in re U.S. Patent Application No. 09/465,338				
241	Communication from the USPTO Office Action mailed 11/18/02 in re U.S. Patent Application No. 09/465,338				

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242	02/07/02 Interview Summary in re U.S. Patent Application No. 09/567,451				
243	Communication from the USPTO Office Action mailed 11/18/02 in re U.S. Patent Application No. 09/567,451				
244	U.S. Patent No. 4,515,805			R	
245	U.S. Patent No. 6,197,347			R	
246	Biovailability study on daytime and nighttime use of Tiazac® capsules 360 mg in healthy subjects	BLS 053034 – BLS 053096	April 6, 2007 Meyer Expert Report Exhibit R	R	

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247	FDA Guidance for Industry re Statistical Procedures for Bioequivalence Studies using a Standard Two-Treatment Crossover Design (07/01/92)				
248	Approved Drug Products ("Orange Book"), 27th Edition, FDA (2007) – entry for Cardizem LA and Tiazac			R	
249	Guidance for Industry Food-Effect Bioavailability and Fed Bioequivalence Studies, FDA, CDER (12/02)			R	
250	Letter, dated 04/22/05, from J. Vaughn to G. Buehler	ANDCLA 00003 – ANDCLA 00004			
251	Letter, dated 08/30/05, from J. Vaughn to G. Buehler	ANDCLA 14139 – ANDCLA 14140			

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252	Undated Letter from D. Connner to B. Berry	ANDCLA 102462-ANDCLA 102464	April 9, 2007 Foster Expert Report Exhibit 16	R, H	
253	Andrx ANDA # 77-686 Excerpt	ANDCLA 14267	April 9, 2007 Foster Expert Report Exhibit 19	R	
254	United States Patent Application of X.X. Cheng, et al. for Diltiazem Controlled Release Formulation and Method of Manufacture	ANDCLA 102907-ANDCLA 102973	Qi Dep. Exh. 14A April 9, 2007 Foster Expert Report Exhibit 22		
255	Bodmeier, R., Tableting of coated pellets, *European J. of Pharmaceutics and Biopharmaceutics*, 43 (1997)1-8			H	

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256	Andrx ANDA Transmittal Letter	ANDCLA 63186 – ANDCLA 63187	Jan. 19, 2007 Brenner Expert Declartion Exhibit 10		
257	Eudragit NE 30 D Data Sheet (Info NED-2/e)			H	
258	Eudragit NE 30 D Prospectus (Info NED-1/e)			H	
259	Eudragit Process Technology Sheet (Info V-5/e)			H	
260	Eudragit E (Info E-12/e)			H	
261	Eudragit E Technical Application Pamphlet (Info E-11/e)			H	
262	Eudragit E Standards Sheet (Info E-7/e)			H	

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263	Eudragit RL and RS Prospectus (Info RL/RS-1/e)			H	
264	Andrx Patent Application (generic Cardizem LA)	ANDCLA 102907 - ANDCLA 102942		DU	
265	Executed Batch Records (420 mg)	ANDCLA 00519 - ANDCLA 00619 ANDCLA 00640 - ANDCLA 00652		MD	
266	Compilation	ANDCLA 14901 - ANDCLA 14986 ANDCLA 14988 - ANDCLA 15030		MD	

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		ANDCLA 15061 - ANDCLA 15088 ANDCLA 15119- ANDCLA 15146 ANDCLA 15182- ANDCLA 15210 ANDCLA 15241 - ANDCLA 15269 ANDCLA 15300 - ANDCLA 15315			

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267	Guidance for Industry SUPAC-MR: Modified Release Solid Oral Dosage Forms (September 1997)			R	
268	Andrx ANDA # 77-686 Excerpt	ANDCLA 00375 - ANDCLA 00380	Jan. 19, 2007 Brenner Expert Declaration Exhibit 30 (part 1)		
269	Andrx ANDA # 77-686 Excerpt	ANDCLA 14529 - ANDCLA 14534	Jan. 19, 2007 Brenner Expert Declaration Exhibit 30 (part 2)		
270	Andrx ANDA # 75-401 Excerpt	9358 – 9360 ANDCLA 92868	Jan. 19, 2007 Brenner Expert Declaration Exhibit 31		

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271	Andrx ANDA # 75-401 Bioequivalency Comments	ANDCLA 102016	Jan. 19, 2007 Brenner Expert Declaration Exhibit 32		
272	April 27, 2006 Letter from J. Vaughn to G. Buehler	ANDCLA 107049 - ANDCLA 107050			
273	Chart		April 9, 2007 Brenner Expert Report Exhibit C	H	
274	Chart		April 9, 2007 Brenner Expert Report Exhibit D	H	
275	Chart		April 9, 2007 Brenner Expert Report Exhibit E	H	
276	Chart		April 9, 2007 Brenner Expert Report Exhibit F	H	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
277	Chart		April 9, 2007 Brenner Expert Report Exhibit G	H	
278	Chart		April 9, 2007 Brenner Expert Report Exhibit H	H	
279	Chart		April 9, 2007 Brenner Expert Report Exhibit I	H	
280	Chart		April 9, 2007 Brenner Expert Report Exhibit J	H	
281	USP 23 Excerpts		April 9, 2007 Brenner Expert Report Exhibit 8	H	
282	Andrx ANDA # 77-686 Excerpt	ANDCLA 00140 – ANDCLA 00145	April 9, 2007 Brenner Expert Report Exhibit 9 (part 1)		

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
283	Andrx ANDA # 77-686 Excerpt	ANDCLA 14310 – ANDCLA 14317	April 9, 2007 Brenner Expert Report Exhibit 9 (part 2)		
284	Andrx ANDA # 77-686 Excerpt	ANDCLA 14546 – ANDCLA 14547	April 9, 2007 Brenner Expert Report Exhibit 9 (part 3)		
285	EXHIBIT REMOVED				
286	EXHIBIT REMOVED				
287	Andrx ANDA # 77-686 Excerpt	ANDCLA 00116 – ANDCLA 00122	April 9, 2007 Brenner Expert Report Exhibit 14 (part 1)		
288	Andrx ANDA # 77-686 Excerpt	ANDCLA 14268 – ANDCLA 14302	April 9, 2007 Brenner Expert Report Exhibit 14 (part 2)		

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
289	Excerpt from Andrx Communication to the FDA regarding Andrx ANDA # 77-686	ANDCLA 110703 – ANDCLA 110780	April 9, 2007 Brenner Expert Report Exhibit 14 (part 3)	C	
290	FDA Guidance for Industry: Dissolution Testing of Immediate Release Solid Oral Dosage Forms (08/97)				
291	Merck Index, 12th Edition, Merck & Co., Inc., Whitehouse Station, NJ (1996) pp. 3249, 9051-52				
292	Andrx ANDA # 77-686 Excerpt	ANDCLA 14310, ANDCLA 14315	July 7, 2006 Brenner Expert Report Exhibit 8		
293	EXHIBIT REMOVED				

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294	United States Patent Application of X.X. Cheng, et al. for Diltiazem Controlled Release Formulation and Method of Manufacture	ANDCLA 102907-ANDCLA 102972 ANDCLA 105869-ANDCLA 105874	July 7, 2006 Brenner Expert Report Exhibit 13	DU	
295	Andrx ANDA # 77-686 Excerpt	ANDCLA 00116-ANDCLA 00120	July 7, 2006 Brenner Expert Report Exhibit 14 (part 1)		
296	EXHIBIT REMOVED				
297	July 16, 2002 Letter from W. Kreppner to D. Throckmorton, M.D.	BLS 007399 – BLS 007428	July 7, 2006 Brenner Expert Report Exhibit 15		
298	Andrx ANDA # 77-686 Excerpt	ANDCLA 15604 – ANDCLA 15615	July 7, 2006 Brenner Expert Report Exhibit 16	C	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
299	Biovail NDA 21-392 Excerpt	BLS 003818, BLS 004634	July 7, 2006 Brenner Expert Report Exhibit 17	C	
300	Andrx ANDA # 77-686 Excerpt	ANDCLA 00880 – ANDCLA 00881, ANDCLA 15701	July 7, 2006 Brenner Expert Report Exhibit 18	C	
301	Biovail NDA 21-392 Excerpt	BLS 004633	July 7, 2006 Brenner Expert Report Exhibit 19	R	
302	Undated Letter from D. Copner (FDA) to B. Berry (Andrx)	ANDCLA 00125 – ANDCLA 00127		R, H	
303	U.S. Patent No. 6,524,620			R	
304	Charts		July 7, 2006 Brenner Expert Report Exhibit 21	H	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
305	Andrx ANDA # 77-686 Excerpt	ANDCLA 00358	July 7, 2006 Brenner Expert Report Exhibit 22		
306	Andrx ANDA # 77-686 Excerpt	ANDCLA 14518	July 7, 2006 Brenner Expert Report Exhibit 23		
307	Jan. 19, 2007 Declaration of Gerald S. Brenner, Ph.D.			H	
308	March 23, 1992 Communication from the USPTO in re USSN 07/721,396				
309	June 22, 1992 Submission to the USPTO in re USSN 07/721,396				
310	EXHIBIT REMOVED				
311	Sept. 25, 1992 Communication from the USPTO in re USSN 07/721,396				

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312	Dec. 26, 1995 Communication from the USPTO in re USSN 08/311,722				
313	May 8, 2000 Submission to USPTO in re USSN 09/567,451				
314	May 25, 2001 Communication from the USPTO in re USSN 09/567,451				
315	Dec. 14, 1995 Submission to the USPTO in re USSN 08/311,722				
316	Cardizem LA Promotional Materials	BLS 020736 – BLS 020747		H, R	
317	Cardizem LA Promotional Materials	BLS 020748 – BLS 020752		H, R	
318	Cardizem LA Promotional Materials (Consider the evidence surrounding BP rise during early morning hours)			H, R, NP/A	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
319	Cardizem LA Promotional Materials (Bringing Unique Technology to Established Antihypertensive Control)			H, R, NP/A	
320	Specifications and test methods for EUDRAGIT® E 12,5 EUDRAGIT® E 100	B 012517 – B 012519		H	
321	Specifications and test methods for EUDRAGIT® NE 30 D	B 012537 – B 012539		H	
322	EXHIBIT REMOVED				
323	Diltiazem HCl ER Pellets Investigation Report No. 00-054: Out of Specification, DI Water Dissolution, Product code: 151	ANDCLA 101506 – ANDCLA 101513	Jan Dep. Exh. 76	W	
324	Letter, dated 01/05/01, from D. Servello to G. Beuhler (FDA)	ANDCLA 101440- ANDCLA 101443	Jan Dep. Exh. 85		

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325	E-mail, dated 06/26/01, from C-M Cheng to D. Trieu, D. Rivera, S. Jan, X.X. Cheng re TZ	ANDCLA 38343	Jan Dep. Exh. 86		
326	Process Validation, dated 01/12/01 (Document No. PVP-054), for the Diltiazem HCl ER Pellets (TZ)	ANDCLA 101372-ANDCLA 101386	Jan Dep. Exh. 89		
327	Book Chapter: Qiu, Yihong, and Zhang, Guohua, Research and Development Aspects of Oral Controlled-Release Dosage Forms, in *Handbook of Pharmaceutical Controlled Release Technology*, Wise, Donald L. (ed.), Marcel Dekker, Inc. New York		Zhang Dep. Exh. 92	H, R	
328	E-mail (string), dated 03/24/05, from G. Zhang to B. Berry re Meeting Summary (redacted)	ANDCLA 82670 – ANDCLA 82672	Zhang Dep. Exh. 95	W	

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329	ANDA 77-686 Minor Amendment from FDA (02/10/06)	ANDCLA 103013-ANDCLA 103017	Vaughn Dep. Exh. 27		
330	WO 01/41744 A1		Zhang Dep. Exh. 96	R	
331	Biovail's Rule 30(b)(6) Notice to Andrx (03/09/06)		Vaughn Dep. Exh. 18	W	
332	Generic Sales and GP Summary, 2005-2008 (Three-Year Business Plan)	ANDCLA 103116	Rosenthal Dep. Exh. 59	R	
333	Collection of Various Andrx Request for Analysis Documents	ANDCLA 102551, 102550, 51961, 52121, 50824, 50816, 62550, 50938, 50821, 51094, 51046, 50546, 51096, 50483, 50401, 62467, 50470, 50510, 62643,	Dixit Dep. Exh. 4	MD	

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
		62917, 62957, 62753, 62913, 62670, 62898, 61244, 62814, 61622, 61296, 61291, 62435, 63127, 62173, 62279, 62238, 60816, 63087, 63076, 61549, 63028, 62207, 61488, 61572, 61611, 102560, 60662, 61710, 61619, 61105, 61805, 61184, 62363, 63021, 61239, 61212, 61388, 41858, 61706, 41923, 41922, 61702, 47386, 104763, 47442, 47844, 104818, 60983, 61176, 61342, 60774, 60719, 60930, 104336, 61518, 42055, 42048, 42006, 105313, 105367, 51289, 62085, 102476, 102477			

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Exhibit No. PTX	Description	Bates	Previous Designation	Objections	Response to Objections
334	File History of U.S. Patent Application USSN 09/119,323	ANDCLA 22871 – ANDCLA 22963	Jan Dep. Exh. 69	NPI, A, R	
335	Validation Report for Diltiazem HCl ER Pellets (TZ) Doc. No. PVR-054 (02/22/01)	ANDCLA 109598-ANDCLA 109685	Cheng Dep. Exh. 108		
336	Diltiazem HCl ER Pellets (TZ): Optimization of Processing Parameters and the Effect of Stability Doc. No. PVR-054 (02/21/01)	ANDCLA 109585-ANDCLA 109597	Cheng Dep. Exh. 109		
337	Feb. 17, 2006 Letter from Anthony H. Son, Andrx's Counsel, to Preston K. Ratliff II			W	
338	File History for Pending U.S. Application No. 09/465,338	ANDCLA 34696 – ANDCLA 35610		NPI, A	

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339	File History for Abandoned U.S. Application No. 09/567,451	ANDCLA 35611 – ANDCLA 36666		NPI, A	
340	Various Demonstratives			NPI	
341	U.S. Pat. No. 5,000,000			R, NP/A	
342	Submission Log relating to ANDA No. 77-686	ANDCLA 14137			
343	Certified File History of U.S. Patent Application No. 08/311,722, U.S. Patent No. 5,529,791			NP/A, NPI. Provided too late to reconcile discrepancies	
344	Certified File History of U.S. Patent Application No. 09/567,451, U.S. Patent No. 7,108,866			NP/A, NPI, Provided too late to inspect	
345	Certified File History of U.S. Patent Application No. 09/465,338 (Abandoned)			NP/A, NPI, Provided too late to inspect	

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